

WE CLAIM:

1. A medical device for insertion into a bodily vessel to treat an aneurysm, the device comprising:
 - 5 a mechanically expandable device expandable from a first position to a second position, said mechanically expandable device is expanded radially outwardly to the second position such that the exterior surface of said mechanically expandable engages with the inner surface of the vessel so as to maintain a fluid pathway through said vessel; and
 - 10 a membrane expandable from a first position to a second position in response to expansion of said mechanically expandable device, said membrane obstructing blood circulation to the aneurysm when expanded to the second position, and at least a portion of the membrane is secured to the mechanically expandable device to maintain the position of the membrane relative to the mechanically expandable device when expanded to the second position.
2. The device of claim 1, wherein the mechanically expandable device comprises a generally tubular structure having an exterior surface defined by a plurality of interconnected struts having interstitial spaces therebetween.
- 20 3. The device of claim 1, wherein the membrane is made of a biocompatible and elastomeric polymer.
4. The device of claim 1, wherein the membrane has a thickness of about 0.001 to 0.005" with pore or hole sizes of about 20 to 100 microns.
- 25 5. The device of claim 1, wherein the membrane is made from polymeric material or biodegradable material.
- 30 6. The device of claim 5, wherein the biodegradable material forms multiple sub-layers mixed with drugs or reagents.
7. The device of claim 1, wherein the membrane is capable of isotropic expansion.
- 35 8. The device of claim 1, wherein the membrane is disposed on the exterior surface of the device.

9. The device of claim 1, wherein the membrane completely surrounds the device.
- 5 10. The device of claim 1, wherein the membrane circumferentially surrounds a portion of the device.
11. The device of claim 1, wherein the membrane covers a portion of the device.
- 10 12. The device of claim 1, wherein the membrane is non-porous and non-permeable to prevent blood circulation to the aneurysm.
13. The device of claim 12, wherein the membrane is made from a solid polymer.
14. The device of claim 1, wherein the membrane is permeable and porous.
- 15 15. The device of claim 14, wherein the membrane has holes or pores such that blood supply to perforations and microscopic branches of main brain arteries is permitted but blood supply to the aneurysm is prevented.
16. The device of claim 15, wherein the membrane has pores between 20 to 100 microns in size.
- 25 17. The device of claim 15, wherein the membrane has fabricated holes between 20 to 100 microns in size.
18. The device of claim 17, wherein the holes are fabricated by laser drilling.
- 30 19. The device of claim 16 or 17, wherein the distance between the pores or holes is less than 100µm.
20. The device of claim 14, wherein the membrane comprises a plurality of polymeric strips secured to the mechanically expandable device

21. The device of claim 20, wherein the strips are less than 0.075mm and the distance between adjacent strips is less than 100 μ m.
22. The device of claim 14, wherein the membrane comprises a mesh secured to the mechanically expandable device.
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23. The device of claim 22, wherein spaces of the mesh is less than 100 μ m and the width of the meshing is between 0.025 to 0.050mm.
- 10 24. The device of claim 1, wherein the aneurysm is a regular size, giant or wide neck aneurysm.
25. The device of claim 1, wherein the mechanically expandable device is self-expandable or balloon expandable.
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26. The device of claim 1, wherein the mechanically expandable device is a stent.
27. The device of claim of claim 2, wherein the membrane is supported by the generally tubular structure and is attached to at least one strut.
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28. The device of claim 26, wherein the membrane is tubular having a diameter similar to a nominal initial diameter of the stent; and wherein the membrane is disposed onto the outer surface of the stent or introduced by dip coating or spraying between the struts of the stent.
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29. The device of claim 26, wherein the membrane is a segment of a tubular structure disposed onto a portion of the outer surface of the stent.
- 30 30. The device of claim 6, wherein the at least one reagent is in any one form selected from the group consisting of: solid tablet, liquid and powder.
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31. The device of claim 1, wherein at least one radiopaque marker is provided on the mechanically expandable device to improve visibility of the device during and after insertion.

32. The device of claim 31, wherein the at least one radiopaque marker is made from gold or platinum.
33. The device of claim 31, wherein center radiopaque markers and end radiopaque markers are provided on the mechanically expandable device.
34. A medical device for treating a bifurcation or trifurcation aneurysm between at least two bodily vessels, the device comprising:
10 a first mechanically expandable device for inserting into a first vessel;
a second mechanically expandable device for inserting into a second vessel;
each mechanically expandable device expandable from a first position to a second position, said mechanically expandable device is expanded radially outwardly to the second position such that the exterior surface of said mechanically
15 expandable device engages with the inner surface of the vessel so as to maintain a fluid pathway through said vessel; and
a membrane expandable from a first position to a second position in response to expansion of said mechanically expandable devices, said membrane obstructing blood circulation to the aneurysm when expanded to the second position, and at least a portion of the membrane is secured to each mechanically
20 expandable device to maintain the position of the membrane relative to the mechanically expandable devices when expanded to the second position.
35. A method of making a medical device according to claim 1, the method comprising:
25 disposing the generally tubular structure on a mandrel; and
disposing the membrane onto the outer surface of the mechanically expandable device.
- 30 36. A method of making a medical device according to claim 26, the method comprising:
disposing the generally tubular structure on a mandrel; and
incorporating the membrane between the struts of the stent.
- 35 37. The method of claim 35 or 36 wherein the disposing is any one selected from the group consisting of: spraying, suture, lamination, adhesion, heat and dip coating.

38. The device of claim 26, wherein the stent is delivered to the aneurysm by a delivery catheter.

AMENDED CLAIMS

[Received by the International Bureau on 07 April 2005 (07.04.2005):
original claims 1-38 replaced by amended claims 1-36]

5 WE CLAIM:

1. A medical device for insertion into a bodily vessel to treat an intracranial aneurysm, the device comprising:

10 a mechanically expandable device expandable from a first position to a second position, said mechanically expandable device is expanded radially outwardly to the second position such that the exterior surface of said mechanically expandable device engages with the inner surface of the vessel so as to maintain a fluid pathway through said vessel; and

15 a membrane expandable from a first position to a second position in response to expansion of said mechanically expandable device, said membrane being positioned proximal to the aneurysm and obstructing blood circulation to the aneurysm when expanded to the second position, and at least a portion of the membrane is secured to the mechanically expandable device to maintain the position of the membrane relative to the mechanically expandable device when 20 expanded to the second position;

wherein the membrane is permeable and porous, the holes or pores of the membrane being such that blood supply to perforations and microscopic branches of main brain arteries is permitted but blood supply to the aneurysm is prevented.

25 2. The device of claim 1, wherein the mechanically expandable device comprises a generally tubular structure having an exterior surface defined by a plurality of interconnected struts having interstitial spaces therebetween.

30 3. The device of claim 1, wherein the membrane is made of a biocompatible and elastomeric polymer.

4. The device of claim 1, wherein the membrane has a thickness of about 0.001 to 0.005" with pore or hole sizes of about 20 to 100 microns.

35 5. The device of claim 1, wherein the membrane is made from polymeric material or biodegradable material.

6. The device of claim 5, wherein the biodegradable material forms multiple sub-layers mixed with drugs or reagents.

- 5 7. The device of claim 1, wherein the membrane is capable of isotropic expansion.
8. The device of claim 1, wherein the membrane is disposed on the exterior surface of the device.
- 10 9. The device of claim 1, wherein the membrane completely surrounds the device.
- 15 10. The device of claim 1, wherein the membrane circumferentially surrounds a portion of the device.
11. The device of claim 1, wherein the membrane covers a portion of the device.
- 20 12. The device of claim 1, wherein the membrane is non-porous and non-permeable to prevent blood circulation to the aneurysm.
13. The device of claim 12, wherein the membrane is made from a solid polymer.
- 25 14. The device of claim 1, wherein the membrane has pores between 20 to 100 microns in size.
- 30 15. The device of claim 1, wherein the membrane has fabricated holes between 20 to 100 microns in size.
16. The device of claim 15, wherein the holes are fabricated by laser drilling.
- 35 17. The device of claim 14 or 15, wherein the distance between the pores or holes is less than 100µm.
18. The device of claim 1, wherein the membrane comprises a plurality of polymeric strips secured to the mechanically expandable device
- 40 19. The device of claim 20, wherein the strips are less than 0.075mm and the distance between adjacent strips is less than 100µm.

- 5 20. The device of claim 1, wherein the membrane comprises a mesh secured
to the mechanically expandable device.
- 10 21. The device of claim 20, wherein spaces of the mesh is less than 100 μm
and the width of the meshing is between 0.025 to 0.050mm.
- 15 22. The device of claim 1, wherein the aneurysm is a regular size, giant or
wide neck aneurysm.
- 20 23. The device of claim 1, wherein the mechanically expandable device is self-
expandable or balloon expandable.
- 25 24. The device of claim 1, wherein the mechanically expandable device is a
stent.
- 30 25. The device of claim of claim 2, wherein the membrane is supported by the
generally tubular structure and is attached to at least one strut.
- 35 26. The device of claim 24, wherein the membrane is tubular having a
diameter similar to a nominal initial diameter of the stent; and wherein the
membrane is disposed onto the outer surface of the stent or introduced by dip
coating or spraying between the struts of the stent.
- 40 27. The device of claim 24, wherein the membrane is a segment of a tubular
structure disposed onto a portion of the outer surface of the stent.
28. The device of claim 6, wherein the at least one reagent is in any one form
selected from the group consisting of: solid tablet, liquid and powder.
29. The device of claim 1, wherein at least one radiopaque marker is provided
on the mechanically expandable device to improve visibility of the device during
and after insertion.
30. The device of claim 29, wherein the at least one radiopaque marker is
made from gold or platinum.
31. The device of claim 29, wherein center radiopaque markers and end
radiopaque markers are provided on the mechanically expandable device.

- 5 32. A medical device for treating a bifurcation or trifurcation intracranial aneurysm between at least two bodily vessels, the device comprising:
 a first mechanically expandable device for inserting into a first vessel;
 a second mechanically expandable device for inserting into a second vessel;
10 each mechanically expandable device expandable from a first position to a second position, said mechanically expandable device is expanded radially outwardly to the second position such that the exterior surface of said mechanically expandable device engages with the inner surface of the vessel so as to maintain a fluid pathway through said vessel; and
15 a membrane expandable from a first position to a second position in response to expansion of said mechanically expandable devices, said membrane being positioned proximal to the aneurysm and obstructing blood circulation to the aneurysm when expanded to the second position, and at least a portion of the membrane is secured to each mechanically expandable device to maintain the position of the membrane relative to the mechanically expandable devices when expanded to the second position;
 wherein the membrane is permeable and porous, the holes or pores of the membrane being such that blood supply to perforations and microscopic branches of main brain arteries is permitted but blood supply to the aneurysm is prevented.
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20 33. A method of making a medical device according to claim 1, the method comprising:
 disposing the generally tubular structure on a mandrel; and
 disposing the membrane onto the outer surface of the mechanically expandable device.
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35 34. A method of making a medical device according to claim 24, the method comprising:
 disposing the generally tubular structure on a mandrel; and
 incorporating the membrane between the struts of the stent.
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45 35. The method of claim 33 or 34 wherein the disposing is any one selected from the group consisting of: spraying, suture, lamination, adhesion, heat and dip coating.
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55 36. The device of claim 24, wherein the stent is delivered to the aneurysm by a delivery catheter.